Application No.: 10/617,624 6 Docket No.: 595792000300

Response to OA of 9/28/05

## <u>REMARKS</u>

# I. STATUS OF CLAIMS

Claims 1, 9 to 11 and 17 to 21 have been amended. New claims 22-30 are added. Claims 12 to 16 have been cancelled without prejudice or disclaimer.

Claim 1 has been amended to recite a transgenic plant comprising seeds with normal or near normal fatty acid composition, where the plant expresses a recombinant plant-derived NHX-type transporter protein when cultivated under a salt concentration that causes at least a relative yield decrease of 25 percent in a plant lacking recombinant plant-derived NHX-type transporter protein. Support for this amendment can be found in the specification, for example, at page 2, paragraph 8; page 9, paragraph 35; and page 48, Table IV.

Claim 17 has been amended to recite a recombinant plant-derived NHX-type transporter protein, including, but not limited to, a nucleic acid molecule of SEQ ID NO:1, a nucleic acid molecule encoding the same amino acid sequence as encoded by SEQ ID NO:1, and a nucleic acid with 95% sequence identity to SEQ ID NO:1. Support for this amendment is found throughout the specification, for example at page 11 bridging to page 13, paragraphs 41 to 43.

Since the specification provides support for each of the above amendments, entry of these amendments is thus respectfully requested.

New claims 22-30 are added. These claims are supported throughout the specification as filed, in particular at paragraph 84.

Cancellation and amendment of the claims is made without prejudice, without intent to abandon any originally claimed subject matter, and without intent to acquiesce in any rejection of record. Applicant expressly reserves the right to file one or more continuing applications hereof containing the cancelled or unamended claims.

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### II. REQUEST FOR EXAMINER INTERVIEW

Applicant respectfully requests that the Examiner contact the undersigned to schedule an interview to discuss in further detail the arguments set forth in this Office Action.

#### III. INFORMATION DISCLOSURE STATEMENT

The Examiner has noted that legible copies of citations 35-38 were not provided with the IDS. A copy of citation #37 is enclosed. Applicant request that the Examiner consider this Abstract, initial the PTO/SB/ 08a/b and return the signed form form for Applicant's file. Citations 35, 36 and 38 refer to oral presentations of the inventor. As far as Applicant can determine, Applicant does not have copies of the presentation slides for citations 35, 36 and 38.

## REJECTION UNDER 35 U.S.C. § 112, 2nd paragraph

Claims 1-21 have been rejected under 35 U.S.C. § 112, 2nd paragraph, for being indefinite.

#### A. Terms "near" and "high"

First, the Office Action alleges that the terms "near" and "high" are relative terms that have no definite meaning.

Applicant traverses the rejection with respect to the term "near" as used in the limitation "normal or near normal fatty acid composition." The fact that claim language, including terms of degree, may not be precise, does not automatically render the claim indefinite under 35 U.S.C. § 112, second paragraph. Seattle Box Co., v. Industrial Crating & Packing, Inc., 731 F.2d 818, 221 USPQ 568 (Fed. Cir. 1984). Acceptability of the claim language depends on whether one of ordinary skill in the art would understand what is claimed, in light of the specification. MPEP § 2173.05(b). In this application, the specification clearly points out that the fatty acid distribution is considered to be "nearly normal" when it is within 3 to 10 percent of the fraction of the same major fatty acid in oil produced by the corresponding plant grown in low to moderate salt. See

specification, page 8, paragraph 30. Further, the specification provides that a "major" fatty acid is a fatty acid that is greater than 5% of the oil at page 8, paragraph 29. Claim 1 and new claim 22 (and those dependent thereon) recite this 5% limitation to provide clarity to the claims. Thus, one of skill of the art would readily be able to ascertain what is claimed in light of the specification.

Applicant asserts that the rejection with respect to the term "high" is now moot.

Applicant has amended the limitation specifying salt levels to recite a "salt concentration that causes at least a relative yield decrease of 25 percent in a plant lacking said recombinant plant-derived NHX-type transporter protein."

## B. Term "fatty acid distribution"

Next, the Office Action alleges that the term "fatty acid distribution" is unclear.

Applicant asserts that the rejection is now moot since the Examiner's suggestion has been followed and the claims have been amended to instead recite a "fatty acid composition."

## C. <u>Term "optimal osmolality"</u>

Finally, the Office Action alleges that the term "optimal osmolality" is awkward and confusing and unclear. Applicant asserts that the rejection is now moot because claims 3-8 have been amended the claim to recite an "optimal saline concentration for growth."

In view of the above amendment and remarks, Applicant thus respectfully requests that the rejection be withdrawn.

# IV. REJECTION UNDER 35 U.S.C. § 112, 1st PARAGRAPH: ENABLEMENT

## A. <u>Claims 1-21</u>

Claims 1-21 have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly not being enabled for all non-naturally occurring non-halophyte oil crop plants comprising seeds with normal fatty acid distribution when cultivated in high salt. Specifically, the Examiner asserts that

the claims are not enabled due to a lack of specific guidance regarding how to make such plants via methods other than transformation. The Examiner also asserts that the specification does not enable plants comprising genes other than SEQ ID NO:1 (Office Action, page 4 to 5).

Applicant asserts that in view of the amendments, the rejection with respect to enablement of non-naturally occurring oil crop plants produced by methods other than transformation is moot. The newly amended claims recite transgenic plants only. Specific guidance regarding methods of transformation and suitable vectors is provided in paragraphs 69 to 76 of the specification.

With respect to rejection regarding the enablement of plants comprising other salt-tolerant genes, including other members of the vacuolar NHX-type transporter gene family, Applicant respectfully disagrees. Accordingly, Applicant respectfully submits that the amended claims to transgenic plants expressing a recombinant plant-derived NHX-type transporter protein are enabled.

Enablement of an invention only requires disclosure of one method of making and using the claimed invention. MPEP § 2164.01(b) The invention here is a composition, a plant which has a seeds with normal or near normal fatty composition despite cultivation in high salt conditions which cause a 25% yield decrease in a plant lacking the recombinant plant-derived NHX-type transporter protein. Throughout the specification, Applicant describes how to make and use this composition by expressing a plant-derived NHX-type transporter protein (At NHX-1) in an oil seed crop (canola) and thus fully describes a method sufficient to enable the claimed invention. Indeed, Applicant goes far beyond the minimum requirement for enablement by describing 36 additional members of the plant-derived NHX-type transporter protein family in Table III.

Furthermore, enablement does not require a working example of each embodiment of the invention, particularly where practice of the other embodiments would be predictable. MPEP § 2164.02. Practice of this invention with plant-derived NHX-type transporter proteins other than *Arabidopsis* NHX-1, such as the ones listed in Table III, is predictable. Predictability does not

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require that one of skill in the art know with certainty whether expression of these other proteins will also result in the claimed composition, but merely that the experimentation required to determine whether such proteins will work is routine. To determine whether a particular plant-derived NHX-type transporter protein would result in the claimed composition, one of skill would simply need to screen using methods known in the art and described herein for evaluating seed fatty acid composition.

### B. Claim 17

Claim 17 has been rejected as not being enabled for additional reasons. In particular, the Office Action points out that molecules hybridizing to SEQ ID NO:1 itself would not encode a NHX1 coding strand since they would be complementary to the sequence. Further, the Office Action alleges that undue experimentation would be required to test unrelated nucleotide sequences that hybridize under moderately stringent conditions.

Applicant has amended claim 17 to omit the recitation of nucleic acid molecules that hybridize to SEQ ID NO:1 and thus respectfully asserts that both portions of this rejection are moot. In view of the above amendments and remarks, Applicant respectfully requests that the enablement rejection be withdrawn.

# V. REJECTION UNDER 35 U.S.C. § 112, 1st PARAGRAPH: WRITTEN DESCRIPTION

Claims 1-21 have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking written description support in the specification. In particular, the Examiner alleges that the specification only provides support for plants comprising SEQ ID NO:1, not the entire genus of plants broadly claimed.

Applicant respectfully disagrees and submits that the specification provides sufficient detail to convey to one of skill in the art that the inventor had possession of the invention described

in the amended claims reciting a transgenic plant expressing a recombinant plant-derived NHX-type transporter protein.

The written description requirement for a genus may be satisfied through sufficient description of a representative number of species by disclosure of relevant identifying characteristics such as *structure* or other physical and/or chemical property, by functional characteristics coupled with a known or disclosed *correlation between function and structure*, or by a combination of such identifying characteristics. MPEP § 2193(II)(A)(3)(a)(ii).

Applicant has provided ample evidence of structure sufficient to satisfy written description. The claimed invention is a plant composition, the structure of which is explicitly disclosed in the specification as a plant with seeds with normal or near normal fatty composition despite cultivation in high salt conditions which cause a 25% yield decrease in a plant lacking a recombinant plant-derived NHX-type transporter protein. This structure is described throughout the specification, and in particular, in the Example on page 25, paragraphs 81 to 83 and Table II.

Applicant has also provided nucleotide structure and structure/function correlation sufficient to demonstrate to one of skill in the art that he had possession of the entire genus of claimed plant compositions at the time of filing. In total, the specification provides 37 examples of amino acid sequences encoding plant-derived NHX-type transporter proteins (Table III, page 35). One of skill in the art is well aware that analysis of this many sequences permits identification of conserved regions potentially conferring an ability to induce normal fatty acid composition. Therefore, given this information, one of skill would readily conclude that Applicant had possession of the genus of plant compositions comprising plant-derived NHX-type transporter proteins. In fact, as shown by the bolded amino acids in Table III, Applicant has done precisely this type of analysis for the first 18 sequences, thus providing further proof of his possession of the invention as claimed.

In view of the above amendments and remarks, Applicant respectfully requests that the enablement rejection be withdrawn

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## VI. REJECTION UNDER 35 U.S.C. § 102(b)

The Examiner has rejected claims 1, 2, and 3 under 35 U.S.C. § 102(b) as being anticipated by Dierig *et al.* ("Dierig"). The Examiner has also rejected claims 1-6, 9 and 11 as being anticipated by Yermanos *et al.* ("Yermanos").

In view of the amendments, Applicant asserts that the rejection is now moot. Anticipation requires that a single reference disclose, either expressly or inherently, each and every element of the claim. As amended, claim 1 recites a transgenic plant expressing a recombinant plant-derived NHX-type transporter protein. Neither Dierig nor Yermanos discloses such a plant expressing a recombinant plant-derived NHX-type transporter protein. Thus, Applicant respectfully requests that the rejection be withdrawn.

#### VII. CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

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In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 595792000300. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: January 30, 2006

Respectfully submitted,

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# Cloning and characterization of plant sodium/proton antiports

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Plants growing in high salinity typically maintain a high ratio of potassium to sodium in the cytosol. The transport of ions across plant membranes is thought to play an important role in maintaining low cytosolic sodium concentrations. Electrogenic proton-translocating pumps generate a protonmotive force that can drive the proton-coupled sodium transport out of the cytosol. Despite the increasing evidence supporting the operation of sodium-proton antiports across plant membranes, the biochemical and molecular identification of the antiport has not been accomplished.

We have cloned a full-length cDNA from *Arabidopsis* that shows a high degree of sequence similarity to yeast, rat, and human sodium/proton exchangers. The longest open-reading frame of this 2.4-kb sequence predicts a protein of 547 amino acids with a conserved amiloride-binding domain and 12 predicted transmembrane domains. High-stringency Southern blot analysis suggested that this gene is present as a single copy in *Arabidopsis*. Northern blot analysis indicated low-level expression of the transcript in all tissues examined (flower, inflorescence stem, leaf, root).

We have also cloned cDNAs from *Arabidopsis* that appear to encode three proteins that show similarity to other sodium/proton exchangers. The three proteins predicted from these cDNAs have 12 transmembrane domains like AtNHX1, but they do not appear to have an amiloride-binding domain. Although AtNHX2 and AtNHX3 show the highest sequence homology to one another, all members of the group (AtNHX2, 3, and 4) have a long hydrophilic C-terminus that is presumably cytoplasmic, and all three of these predicted proteins have a predicted molecular mass on the order of 95-100 kDa. The occurrence of gene families is not unusual in plants, and the finding of putative Na<sup>+</sup>/H<sup>+</sup>-antiport isoforms is certainly not inconsistent with the ability of plant cells to extrude sodium as well as sequester it in endomembrane compartments such as the vacuole. Results of molecular, transgenic, and transport studies will be presented and the possible role of these proteins in the response of higher plants to salt will be discussed.